

I. Status of the Application and Claims

Applicants acknowledge entry of their amendment filed March 31, 2003. Claims 22, 24, 27, 29, 30, and 33 are pending in this application and stand rejected.

Applicants have amended claims 24, 27, and 33 solely to more clearly recite their invention. No new matter is entered by the amendments.

II. Rejections for Lack of Utility/Enablement

The Office has maintained the rejection of claims 22, 24, 27, 29, 30, and 33 under 35 U.S.C. § 101 as allegedly unsupported by either a substantial asserted utility or a well-established utility. Office action, page 2. Based on its assertion that the claimed nucleotide sequences lack utility, the Office also rejects the claims under section 112, first paragraph, for non-enablement. *Id.*, page 4. Applicants traverse these rejections for the reasons of record, supplemented as follows.

In their response filed March 31, 2003, Applicants argued that Example 10 of the Revised Interim Utility Guidelines Training Materials, which describes a hypothetical disclosure of a full Open Reading Frame ("ORF") and identification of the corresponding protein sequence having high homology to a DNA ligase, was relevant to the question of whether the instant nucleotide sequences have utility. The Office was not persuaded by this argument because "unlike the DNA ligase, the potassium channels do not have a known utility." Office action, page 2. Contrary to the Office's position, however, potassium channels do have a known utility recognized by those of skill in the art.

For example, U.S. Patent No. 6,511,824 is directed to two-pore, potassium channel proteins of the TWIK family. The '824 patent claims, among other things,

isolated nucleic acids encoding a TWIK protein. The invention is described as "relat[ing] to novel invertebrate TWIK channel nucleic acid and polypeptide sequences and their uses in genetic screens and compound screening." '824 patent, col. 1, lines 13-15. As background, the '824 patent describes the three potassium channel family of proteins, to one of which the TWIK proteins claimed by in patent belong. *Id.*, col. 1, line 34 to col. 2, line 3. It describes pesticide development, and the fact that "[i]on channels are validated targets for insecticide action." *Id.*, col. 2, lines 4-43. It teaches that "[p]otassium ion channels are involved in numerous cellular functions in a variety of cell types, and recent advances in genomics and physiology have identified several potassium channels that are involved in human diseases." *Id.*, lines 44-48; citation omitted. The '824 patent goes on to add that "[t]he growing body of information regarding the modular subunits and the high-resolution structural [*sic*, structure] of these channels [*sic*, channel] features provide critical information for validation of potassium channels as drug targets." *Id.*, lines 54-58.

Specific utilities for the claimed potassium channel proteins are disclosed, for example at col. 3, lines 8-32, and Examples 5.4 (col. 16) through 5.21 (col. 30) and 6.4 (col. 45). It is worth noting that (1) all of the examples appear to be prophetic, and (2) the inventors never actually test the activity of the protein encoded by the claimed nucleotide sequences. Therefore, there is no utility linked to any unique function of the proteins encoded by the claimed nucleotide sequences. Instead, the utility is based on the fact that potassium channel proteins as a family have utility that is recognized in the art.

This is consistent with the DNA ligase example in the utility guidelines training materials. The hypothetical ORF in Example 10 has utility based on the fact that the protein it encodes has a high level of homology to ligases. The example does not disclose that there is anything unique to the hypothetical DNA ligase, nor that this is needed for the ORF to have utility. Rather, the fact that it exhibits homology to prior DNA ligases, and DNA ligases have a well-established utility in molecular biology, is all that is needed to establish the utility of the novel ORF in the Example.

The Office, in this application, is imposing a higher burden than is demonstrated in Example 10. Here, evidence of homology to known potassium channel proteins of demonstrated utility is held not sufficient to satisfy the utility requirement. In Example 10, as well as for the '824 patent, it is sufficient. There is no requirement that Applicants provide data supporting utility when a utility for a compound is known. Nor is there any basis for the Office to treat the claims of the '824 patent and the claims under rejection in this application differently. If the claims of the '824 patent have utility, then the instant claims also have utility.

The Office has not provided any reason to doubt the uses Applicants disclose in their specification for the claimed nucleotide sequences. Moreover, the Office's statement that "the potassium channels do not have a known utility" is not correct, as shown, for example, by the teaching of the '824 patent. Potassium channel proteins, and the nucleotide sequences encoding them, have many uses based on the known function of these proteins in regulating ion balance in cells. For these reasons,

Applicants request that the Office reconsider and withdraw the rejections for lack of utility/non-enablement

III. Rejection for Lack of Written Description

The Office rejects claims 24, 27, 29-30, and 33 under 35 U.S.C. § 112, first paragraph, as allegedly containing subject matter that is not described in the specification so as to reasonably convey to the person skilled in the art that Applicants were in possession of the claimed invention at the time the application was filed. Office action, page 4. Applicants traverse.

According to the Office, "[t]he newly amended claims now contain structural limitations which are generic and are not limited by functional limitation." *Id.* In response to Applicants' argument that the claims are directed to nucleic acids encoding functional proteins, the Office asserts that "the claims do not recite [a] functional limitation which is specific for the CORK two pore potassium channel." *Id.*, pages 4 and 5. Applicants disagree.

Applicants have amended claim 24 to move the functional language of the "wherein clause" from part (ii) to the end of the claim to more clearly indicate that the language in that clause applies to each of the embodiments in (i-iv) and added the term "CORK" to the functional language. Applicants submit that the amendment addresses the Office's concern that the functional language is not specific to CORK two pore potassium channels.

Furthermore, Applicants direct the Office's attention to Example 9 in the Synopsis of Application of Written Description Guidelines, which provides guidance to Examiners

in applying the written description guidelines. Example 9 addresses hybridization claims and its guidance is relevant to the claims under rejection here. The hypothetical claim analyzed in the Example recites "[a]n isolated nucleic acid that specifically hybridizes under highly stringent conditions to the complement of the sequence set forth in SEQ ID NO: 1, wherein said nucleic acid encodes a protein that binds to a dopamine receptor and stimulates adenylate cyclase activity." According to the Example, this claim is drawn to a genus of nucleic acids that (1) must hybridize to SEQ ID NO: 1 and (2) encode a protein with a specific activity. In analyzing the issue of written description support for the genus claim, the Office indicates that "a person of skill in the art would not expect substantial variation among species encompassed within the scope of the claims because the highly stringent hybridization conditions set forth in the claim yield structurally similar DNAs." The Office concludes that the specification does provide written description support for the claim, even though the nucleotide sequence of only one species is shown, because "highly stringent hybridization conditions in combination with the coding function of DNA and the level of skill and knowledge in the art are adequate to determine that applicant was in possession of the claimed invention."

Applicants submit that the reasoning and guidance provided by Example 9 apply equally to the claims under rejection here. Accordingly, Applicants request that the Office reconsider and withdraw this rejection.

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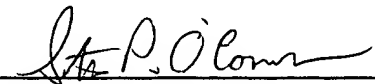
CONCLUSION

In view of these remarks, Applicants respectfully request examination on the merits and timely allowance of the pending claims.

Please grant any extensions of time required to enter this response and charge any additional required fees to our deposit account 06-0916.

Respectfully submitted,

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